

Frequently Asked Questions: Proposed Rule "Required Warnings for Cigarette Packages and Advertisements"

Throughout this document FDA uses the following terms:

- **Graphic Health Warning – refers to the combination of one of the following nine textual warning statements and its accompanying color graphic**
- **Graphic Images – refers only to color graphics depicting the negative health consequences of smoking**
- **Textual Warning Statements – refers to the following nine textual warning statements:**
 - WARNING: Cigarettes are addictive.
 - WARNING: Tobacco smoke can harm your children.
 - WARNING: Cigarettes cause fatal lung disease.
 - WARNING: Cigarettes cause cancer.
 - WARNING: Cigarettes cause strokes and heart disease.
 - WARNING: Smoking during pregnancy can harm your baby.
 - WARNING: Smoking can kill you.
 - WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
 - WARNING: Quitting smoking now greatly reduces serious risks to your health.

General--Proposed Rule

Why is FDA issuing a proposed rule for the new graphic health warnings?

Section 201 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) requires nine new larger and more noticeable textual warning statements to appear on cigarette packages and in cigarette advertisements. It also directs FDA to issue regulations requiring that color graphic images depicting the negative health consequences of smoking accompany the nine new textual warning statements. Once final, they would appear on the upper portion of the front and rear panels of each cigarette package and comprise at least the top 50 percent of these panels. It also requires that they appear in each cigarette advertisement and occupy at least 20 percent of the advertisement.

What is the intended impact of the new proposed graphic health warnings on the health of the American public?

These proposed graphic health warnings would clearly and effectively convey the negative health consequences of smoking. The inclusion of larger and more noticeable graphic health warnings on packages and in advertisements would provide a critical opportunity to educate consumers about the health risks of cigarettes, which would help encourage current smokers to quit, and discourage nonsmokers, including youth, from starting to use cigarettes.

What information is contained in the proposed rule?

The proposed rule, *Required Warnings for Cigarette Packages and Advertisements*, along with section 201 of the Tobacco Control Act, sets out requirements for the display of new graphic health warnings on cigarette packages and in cigarette advertisements. In a separate document, FDA also is publishing electronic files containing 36 proposed graphic health warnings for public comment. FDA encourages interested members of the public to submit either electronic or written comments on this proposed rule and the accompanying proposed graphic health warnings.

What information is FDA seeking from the public?

FDA is seeking comments on the proposed rule. As part of this, FDA is seeking comments on which graphic health warnings it should include in its final regulations, including comments on the color graphics in the proposed graphic health warnings that accompany the proposed rule.

How many proposed graphic health warnings are included with the proposed rule?

A total of 36 proposed graphic health warnings are included in the document accompanying the proposed rule. Two proposed color graphics for use solely in advertisements with a small surface area (i.e., less than 12 square inches) are also included in the document accompanying the proposed rule. After considering the public comments, research results, and scientific literature, FDA intends to select a set of nine required graphic health warnings (from the 36), and one proposed color graphic for use in small surface area advertisements for the final rule.

How will the final nine graphic health warnings be selected?

FDA plans to select a set of nine final graphic health warnings based on their ability to effectively communicate the health risks of smoking to the public. In making its selections, FDA will consider the results of its research on the proposed graphic health warnings, the relevant scientific literature, and the public comments it receives on the proposal. FDA plans to select a set of nine required graphic health warnings comprised of one color graphic image that is paired with one of the nine new textual warning statements required by the Tobacco Control Act.

How many textual warning statements are required by the Tobacco Control Act?

The Tobacco Control Act requires the following nine textual warning statements to appear on cigarette packages and in cigarette advertisements:

- WARNING: Cigarettes are addictive.
- WARNING: Tobacco smoke can harm your children.
- WARNING: Cigarettes cause fatal lung disease.
- WARNING: Cigarettes cause cancer.
- WARNING: Cigarettes cause strokes and heart disease.
- WARNING: Smoking during pregnancy can harm your baby.
- WARNING: Smoking can kill you.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

How much time does the public have to comment on the information in the proposed rule?

The public will have 60 days from the date the proposed rule is published to comment on the information in the proposed rule including the accompanying proposed graphic health warnings. The public will have until January 9, 2011 to officially comment to the docket on the proposed rule.

What happens after the comment period closes?

After the comment period closes, FDA will review all the comments submitted and consider them as the Agency drafts the final rule.

When does FDA have to issue a final rule?

The Tobacco Control Act requires FDA to issue the final rule by June 22, 2011.

When will the graphic health warnings begin to appear on cigarette packages and in advertisements?

The Tobacco Control Act specifies that the requirements for graphic health warnings on cigarette packages and in advertisements are effective 15 months after FDA issues its final rule (no later than September 22, 2012). As of this date, companies will no longer be allowed to manufacture cigarettes without new graphic health warnings on their packaging for sale or distribution in the United States and manufacturers, importers, distributors, and retailers will no longer be allowed to advertise within the United States cigarettes without the new graphic health warnings.

Beginning 30 days after the effective date (no later than October 22, 2012), manufacturers will no longer be allowed to distribute for sale in the United States any cigarettes that do not display the new graphic health warnings.

Will the new textual warnings replace the Surgeon General's warning currently seen on all cigarette packages?

Yes. The Tobacco Control Act requires nine new textual warning statements on cigarettes packages and in advertisements. The Tobacco Control Act requires the use of the nine new textual statements and does not include any reference to the Surgeon General.

Image Design

What are the requirements for placement of the graphic health warnings?

The Tobacco Control Act requires that the nine graphic health warnings appear on the upper portion of the front and rear panels of each cigarette package and comprise at least the top 50 percent of these panels. It also requires that they appear in each cigarette advertisement and occupy at least 20 percent of the advertisement.

Who designed the proposed graphic health warnings?

FDA worked with various experts in the fields of health communications, marketing research, graphic design, and advertising to develop the graphic images used in the proposed graphic health warnings.

What types of images are included in the proposed graphic health warnings?

The set of proposed graphic health warnings encompasses a variety of themes and techniques. The graphic health warnings are designed to communicate important information about the health risks of smoking to a diverse range of audiences, including youth, young adults, adults, smokers, and potential smokers. The images associated with some of the required text warning statements are photographic while others are graphic illustrations. There is also variation in fonts, design, and layouts.

Do other countries use pictorial warnings on cigarette packages?

More than 30 countries/jurisdictions have implemented pictorial warnings on tobacco packages and requirements for pictorial warnings are pending in several other countries/jurisdictions.

How do the images FDA developed compare with those used by other countries that require graphic health warnings?

FDA believes that the proposed graphic health warnings are consistent with the types of pictorial warnings required or developed by other nations or international governmental authorities, such as Canada, the European Union, and Australia. These sets of graphic health warnings include a balance of images.

Was the possibility of “wear-out” considered in the design of the proposed graphic health warnings?

Yes. The overall body of available scientific literature has shown that using a variety of textual warnings statements and accompanying graphic images has been found to be effective in counteracting over-exposure and delaying “wear-out” of health warnings.

Once it issues a final rule, does the law allow for FDA to change the graphic images and/or textual warning statements?

Yes. The Tobacco Control Act permits FDA to adjust the format, type size, color graphics, and textual warning statements of the graphic health warnings if the change would promote greater public understanding of the risks associated with the use of tobacco products. Before making a change under this provision of the Tobacco Control Act, FDA must provide notice and give the public an opportunity to comment.

Will the required graphic health warnings include information to help those who smoke and want to quit?

FDA proposes that one or more of the required graphic health warnings include specified information about an appropriate smoking cessation resource, such as a Website address or a phone number where smokers and other members of the public can obtain factual information to help people stop smoking. FDA is seeking public comment on the selection of an appropriate smoking cessation resource for the final regulation and the criteria that should apply to the resource.

The smoking cessation information would be included as part of one or more of the required graphic health warnings and therefore would not appear outside of the areas specified for the required warning (i.e., 50 percent of the area of each of the front and rear panels of cigarette packages and 20 percent of the area of advertisements).

Research demonstrates that health warnings are more effective if they are combined with cessation-related information, therefore, having a greater public health impact.

Specific to Products and Advertising

Once the rule is final, can FDA instruct cigarette manufacturers to put particular graphic health warnings on particular cigarette brands?

For cigarette packages, the Tobacco Control Act requires that the warning statements be randomly displayed.

More specifically: In each 12-month period, all nine of the different warnings must appear in as equal a number of times as is possible on each brand of cigarettes and be randomly distributed in all areas of the United States in which the product is marketed.

For advertisements, the law requires that the warning statements be rotated quarterly in alternating sequence for each brand of cigarettes. Thus, for ads, the graphic health warning would change every three months.

Will the new graphic health warnings be required on cigarette cartons?

FDA is proposing that the required graphic health warnings appear on the left 50 percent of the front and rear panels of cigarette cartons.

What types of advertisements would be required to include the new graphic health warnings?

Under the proposed rule, all advertisements, regardless of form, would be required to display the graphic health warnings. Advertisements are defined as materials such as magazine and newspaper ads, pamphlets, leaflets, brochures, coupons, catalogues, retail or point-of-sale displays (including functional items such as clocks), posters, billboards, direct mailers, and Internet advertising (e.g., Web pages, banner ads).

Will the graphic health warnings display textual warning statements in languages other than English?

Under the proposal, for cigarette packaging, the textual warning statements would be required to appear in English.

Under the proposal, for cigarette advertisements, the textual warning statements would be required to appear in English, with two exceptions. First, if an advertisement appears in a non-English language publication, the textual warning statement would be required to appear in the predominant language of that publication. Second, if the advertisement appears in an English language publication, but the ad itself is presented in a different language, the textual warning statement would be required to appear in the language principally used in the advertisement.

How will FDA ensure that tobacco manufactures do not alter the cigarette packaging to cover the graphic health warnings?

The proposed rule would require that the graphic health warnings appear directly on cigarette packages and be clearly visible underneath the cellophane or other clear wrapping. Additionally, any other material that is placed on the outside of packages, such as price information or promotional material (e.g., coupons), could not be placed over or otherwise obscure the required graphic health warning.

Research

What research is being conducted to assess the impact of the proposed graphic health warnings?

In addition to seeking public comment, FDA is currently conducting scientific research on the proposed graphic health warnings to: 1) measure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to the proposed graphic images and their accompanying textual warning statements; 2) determine whether consumer responses to the proposed graphic images and their accompanying textual warnings statements differ across various groups based on smoking status, age, ethnicity or race or other demographic variables; and 3) evaluate which are most effective in communicating information about various health risks of smoking, and additionally at encouraging smokers to quit and discouraging non-smokers from starting.

Will the research results be made available to the public?

Once the research is complete and final analyses of the results are available, FDA will place a report of the results of the analyses in the docket and announce the report's availability by a notice in the *Federal Register* so the public has an opportunity to comment on the results.